Non-Confidential Summary of Safety and Effectiveness

JAN 23 2009

15-Sep-08

NeoChild LLC
4605 N Stiles
Oklahoma City, OK 73105

Tel 888-887-6428
Fax 405-813-2905

Official Contact Rhett Bolen – Operations and QA Manager

Proprietary or Trade Name SafeChild Infant Feeding Tube and Accessories

Common/Usual Name Feeding Tube or NG /OG Tube

Classification Name Tubes, Gastrointestinal (and Accessories)

Predicate Devices

NeoChild - Infant Feeding Tubes – K052903
NeoChild – Infant feeding Tube with non-IV connector – K072756
Klein Baker (Utah) – K945012 and K861090 – NutriCath Silicone Feeding Tube and enteral feeding tube extension set
Vygon – K925854 – NutriSafe Polyurethane Feeding Tube
NeoChild – K003854 Intravascular Administration Sets

Device Description

The proposed modification to Infant Feeding Tube and accessories is to add additional materials that the feeding tube may be made from, i e , silicone and polyurethane In addition, we offer accessories an enteral extension set and syringe with non-IV connector These may be sold with the Feeding tubes or separately There is an option of the connectors being standard IV luer lock or a special non-IV connector which was cleared under K072756

The feeding tubes are a small diameter tube of various diameters, 4, 5, 6 5, and 8 French, and various lengths They have an integral female fitting There are 2 eyelets near the tip of the tube They have markings along the shaft of the tubing and an integral radiopaque line They are provided sterile We will offer a non-sterile syringe with the appropriate mating, non-IV connector as part of the package, which was also cleared under K072756

Indications for Use

The Infant Feeding tube is intended to be placed into the stomach to permit the introduction of fluids as directed by the physician Intended for nasogastric or orogastric placement Limited to < 30 day placement Not intended for transpyloric placement

Available in PVC, Silicone or Polyurethane

Environment of Use

Hospital, home, or environments where placement of a feeding tube is required

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Comparison to Predicate Devices

Attribute	**Proposed device with modification**	**Predicates**
Indications General	To be placed into the stomach to permit the introduction of fluids as directed by the physician	To be placed into the stomach to permit the introduction of fluids as directed by the physician K052903 – Infant Feeding Tube K072756 – Infant Feeding Tube and accessories with non-IV connector
Type of placement	Nasogastric or orogastric Not for transpyloric placement	Nasogastric or orogastric Not for transpyloric placement K052903 – Infant Feeding Tube K072756 – Infant Feeding Tube and accessories with non-IV connector
Length of placement	< 30 days	< 30 days K052903 – Infant Feeding Tube K072756 – Infant Feeding Tube and accessories with non-IV connector
Intended for single patient use	Yes	Yes K052903 – Infant Feeding Tube K072756 – Infant Feeding Tube and accessories with non-IV connector
Prescription	Yes	Yes K052903 – Infant Feeding Tube K072756 – Infant Feeding Tube and accessories with non-IV connector
Intended population	Neonates, Infants, Pediatrics	Infants / Pediatrics K052903 – Infant Feeding Tube K072756 – Infant Feeding Tube and accessories with non-IV connector Neonates K945012 – Klein Baker (Utah) NutriCath

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Attribute	Proposed device with modification	Predicates
Intended Environment of Use	Hospital, home, or environments where placement of a Feeding tube is required	Hospital, home or environments where placement of a Feeding tube is required K052903 – Infant Feeding Tube K072756 – Infant Feeding Tube and accessories with non-IV connector
Design Features		
Provided in various diameters from 4 - 8 Fr	4, 5, 6 5, 8 Fr	5, 6 5, 8 Fr K052903 – Infant Feeding Tube K072756 – Infant Feeding Tube and accessories with non-IV connector 4 Fr K925854 – Vygon NutriSafe for 4 Fr size
Extension sets for use with enteral feeding tubes to deliver fluids and connector between the feeding tube and the fluid source	Yes Made of PVC Available in various lengths Intended for use with enteral feeding tubes	Yes K003854 – NeoChild IV extension set Yes K945012 – Klein Baker (Utah) NutriCath with extension set
Connector options	Non-IV slip fit female connection Must be used with the NeoChild syringe with integral mating non-IV connector Standard IV luer	Non-IV K072756 – Infant Feeding Tube and accessories with non-IV connector Standard slip fit female luer K052903 – Infant Feeding Tube
Two (2) eyelet holes near tip	Yes	Yes K052903 – Infant Feeding Tube
Radiopaque line	Yes	Yes K052903 – Infant Feeding Tube
Markings along the length of the tubing	Yes	Yes K052903 – Infant Feeding Tube

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Attribute	Proposed device with modification	Predicates
Materials		
Tubing	PVC Silicone Polyurethane	K052903 – Infant Feeding Tube K072756 – Infant Feeding Tube and accessories with non-IV connector Klein Baker (Utah) – K945012 and K861090 NutriCath Vygon – K925854 - NutriSafe
Packaging		
Sterile	Yes Feeding tubes Extension Sets	Yes K052903 – Infant Feeding Tube K072756 – Infant Feeding Tube and accessories with non-IV connector K003854 – IV extensions sets K945102 – Klein Baker (Utah) NutriCath
Non-sterile	Yes Syringe with integral non-IV Connector	Yes K072756 – Infant Feeding Tube and accessories with non-IV connector
Offered with and without extension sets of various lengths and connectors	Yes	K072756 – Infant Feeding Tube and accessories with non-IV connector
Performance		
None under Section 514	Yes	Yes

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Differences between Other Legally Marketed Predicate Devices

There are no significant differences between the intended device and the predicates –

- NeoChild – K052903 -Infant Feeding Tubes,
- NeoChild – K072756 - Infant feeding Tube with non-IVconnector,
- Klein Baker (Utah) – K945012 and K861090 – NutriCath Silicone Feeding Tube and Enteral Feeding tube extension set,
- Vygon – K925854 – NutriSafe Polyurethane Feeding Tube, and
- NeoChild – K003854 - Intravascular Administration (extension) Sets

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 3 2009

Mr Rhett Bolen
Operations / QA Manager
NeoChild LLC
4605 North Stiles Avenue
OKLAHOMA CITY OK 73105

Re K082710
Trade/Device Name SafeChild Enteral Feeding Tube and Accessories
Regulation Number 21 CFR §876 5980
Regulation Name Gastrointestinal tube and accessories
Regulatory Class Class II
Product Code KNT
Dated January 6, 2009
Received January 12, 2009

Dear Mr Bolen

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter

21 CFR 876 xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884 xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index html.

Sincerely yours,

Janine M Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K082710 (To be assigned)

Device Name: SafeChild Enteral Feeding tube and accessories

Indications for Use:

The Infant Feeding tubes are intended to be placed into the stomach to permit the introduction of fluids as directed by the physician Intended for nasogastric or orogastric placement Limited to < 30 day placement Not intended for transpyloric placement

There are accessory extension sets which are used with the Feeding tubes

The Feeding tubes are available in different materials - PVC, Silicone or Polyurethane

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K082710